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(1) *A coordinated care plan.* A coordinated care plan is a plan that includes a network of providers that are under contract or arrangement with the organization to deliver the benefit package approved by CMS.

(i) The network is approved by CMS to ensure that all applicable requirements are met, including access and availability, service area, and quality.

(ii) Coordinated care plans may include mechanisms to control utilization, such as referrals from a gatekeeper for an enrollee to receive services within the plan, and financial arrangements that offer incentives to providers to furnish high quality and cost-effective care.

(iii) Coordinated care plans include plans offered by health maintenance organizations (HMOs), provider-sponsored organizations (PSOs), preferred provider organizations (PPOs) as specified in paragraph (a)(1)(iv) of this section, RFBs, and other network plans (except network MSA plans).

(iv) A PPO plan is a plan that has a network of providers that have agreed to a contractually specified reimbursement for covered benefits with the organization offering the plan; provides for reimbursement for all covered benefits regardless of whether the benefits are provided within the network of providers; and is offered by an organization that is not licensed or organized under State law as an HMO.

(2) *A combination of an M+C MSA plan and a contribution into the M+C MSA established in accordance with §422.262.* (i) *M+C MSA plan* means a plan that—

(A) Pays at least for the services described in §422.101, after the enrollee has incurred countable expenses (as specified in the plan) equal in amount to the annual deductible specified in §422.103(d); and

(B) Meets all other applicable requirements of this part.

(ii) An M+C MSA plan may be either a network plan or a non-network plan.

(A) *M+C network MSA plan* means an MSA plan under which enrollees must receive services through a defined provider network that is approved by CMS to ensure that all applicable requirements are met, including access and availability, service area, and quality.

(B) *M+C non-network MSA plan* means an MSA plan under which enrollees are not required to receive services through a provider network.

(iii) *M+C MSA* means a trust or custodial account—

(A) That is established in conjunction with an MSA plan for the purpose of paying the qualified expenses of the account holder; and

(B) Into which no deposits are made other than contributions by CMS under the M+C program, or a trustee-to-trustee transfer or rollover from another M+C MSA of the same account holder, in accordance with the requirements of sections 138 and 220 of the Internal Revenue Code.

(3) *M+C private fee-for-service plan.* An M+C private fee-for-service plan is an M+C plan that—

(i) Pays providers of services at a rate determined by the plan on a fee-for-service basis without placing the provider at financial risk;

(ii) Does not vary the rates for a provider based on the utilization of that provider's services; and

(iii) Does not restrict enrollees' choices among providers that are lawfully authorized to provide services and agree to accept the plan's terms and conditions of payment.

(b) *Multiple plans.* Under its contract, an M+C organization may offer multiple plans, regardless of type, provided that the M+C organization is licensed or approved under State law to provide those types of plans (or, in the case of a PSO plan, has received from CMS a waiver of the State licensing requirement). If an M+C organization has received a waiver for the licensing requirement to offer a PSO plan, that waiver does not apply to the licensing requirement for any other type of M+C plan.

[63 FR 35068, June 26, 1998, as amended at 65 FR 40315, June 29, 2000]

§422.6 Application requirements.

(a) *Scope.* This section sets forth application requirements for entities that seek a contract as an M+C organization offering an M+C plan.

(b) *Completion of an application.* (1) In order to obtain a determination on whether it meets the requirements to become an M+C organization and is

qualified to provide a particular type of M+C plan, an entity, or an individual authorized to act for the entity (the applicant) must complete a certified application, in the form and manner required by CMS, including the following:

(i) Documentation of appropriate State licensure or State certification that the entity is able to offer health insurance or health benefits coverage that meets State-specified standards applicable to M+C plans, and is authorized by the State to accept prepaid capitation for providing, arranging, or paying for the comprehensive health care services to be offered under the M+C contract; or

(ii) Federal waiver as described in subpart H of this part.

(2) The authorized individual must describe thoroughly how the entity and M+C plan meet, or will meet, the requirements described in this part.

(c) *Responsibility for making determinations.* CMS is responsible for determining whether an entity qualifies as an M+C organization and whether proposed M+C plans meet the requirements of this part.

(d) *Resubmittal of application.* An application that has been denied by CMS may not be resubmitted for 4 months after the date of the notice from CMS denying the application.

(e) *Disclosure of application information under the Freedom of Information Act.* An applicant submitting material that he or she believes is protected from disclosure under 5 U.S.C. 552, the Freedom of Information Act, or because of exceptions provided in 45 CFR part 5 (the Department's regulations providing exceptions to disclosure), should label the material ''privileged'' and include an explanation of the applicability of an exception described in 45 CFR part 5.

§ 422.8 Evaluation and determination procedures.

(a) *Basis for evaluation and determination.* (1) CMS evaluates an application for an M+C contract on the basis of information contained in the application itself and any additional information that CMS obtains through on-site visits, public hearings, and any other appropriate procedures.

(2) If the application is incomplete, CMS notifies the contract applicant and allows 60 days from the date of the notice for the contract applicant to furnish the missing information.

(3) After evaluating all relevant information, CMS determines whether the contract applicant's application meets the applicable requirements of § 422.6.

(b) *Use of information from a prior contracting period.* If an M+C organization, HMO, competitive medical plan, or health care prepayment plan has failed to comply with the terms of a previous year's contract with CMS under title XVIII of the Act, or has failed to complete a corrective action plan during the term of the contract, CMS may deny an application from a contract applicant based on the contract applicant's failure to comply with that prior contract with CMS even if the contract applicant meets all of the current requirements.

(c) *Notice of determination.* CMS notifies each applicant that applies for an M+C contract under this part of its determination and the basis for the determination. The determination may be approval, intent to deny, or denial.

(d) *Approval of application.* If CMS approves the application, it gives written notice to the contract applicant, indicating that it meets the requirements for an M+C contract.

(e) *Intent to deny.* (1) If CMS finds that the contract applicant does not appear to meet the requirements for an M+C organization and appears to be able to meet those requirements within 60 days, CMS gives the contract applicant notice of intent to deny the application for an M+C contract and a summary of the basis for this preliminary finding.

(2) Within 60 days from the date of the notice, the contract applicant may respond in writing to the issues or other matters that were the basis for CMS's preliminary finding and may revise its application to remedy any defects CMS identified.

(f) *Denial of application.* If CMS denies the application, it gives written notice to the contract applicant indicating—

(1) That the contract applicant does not meet the contract requirements under part C of title XVIII of the Act;